DISCUSSION

Dr Zachary K. Baldwin (*Jackson, Miss*). Despite the lack of high-quality evidence for efficacy, percutaneous access for endovascular aneurysm repair has become commonplace among vascular interventionalists. In the right hands, it has the potential to mitigate the morbidity associated with open groin incision, speed recovery, and accelerate discharge. However, in the wrong hands and without proper training and judgment, there is the potential for grave complication.

With this in mind and with CMS looking over everyone's shoulder in terms of outcomes data and reimbursement, the authors should be commended on putting together a thoughtful multicenter trial of percutaneous EVAR and traditional EVAR. The study provides level 1 evidence of noninferiority when comparing percutaneous to open access. From a clinical standpoint, PEVAR was found to either trend toward or significantly impact procedure time, time to hemostasis, blood loss, and mean time to hospital discharge. The study outcomes suggest that PEVAR has favorable impact on the perioperative course of EVAR patents. Given the stent graft utilized, French size, and closure device, these results appear to be applicable to other EVAR devices on the market.

That being said, the core question of comparative effectiveness research is which treatment works best, for whom, and under what circumstances? Answering these questions using this study is somewhat difficult given that the patient cohort is notable for being predominantly white males with large iliac vessels and average BMIs <30. The morbidly obese are thought to be a group likely to benefit from a percutaneous approach. However, it is difficult to confirm or deny these suspicions based on this particular study. Iliac morphology may also play a role in deciding between percutaneous and open vessel access. It has been my experience that advancing and withdrawing sheaths in borderline diameter arteries with significant calcification and/or tortuosity can increase shear at the level of arteriotomy. Are such cases better approached percutaneously, or does open exposure mitigate potential injury?

Finally, one potential benefit of percutaneous access is allowing for an "awake" EVAR. Avoidance of a general anesthetic should have an impact in terms of perioperative morbidity/mortality when performing EVAR. Unfortunately, there is little information as to whether utilization of PEVAR impacted anesthetic choice among participating physicians.

Dr Nelson and colleagues should be congratulated on a very important and timely study that provides much needed evidence for percutaneous access in performance of EVAR. I do not believe that the study can be interpreted by interventionalists as a license to access all patients percutaneously. Instead, the study provides clear evidence of the percutaneous technique's safety and will, hopefully, set the stage for studies in the future defining which patients benefit most from a percutaneous approach.

Dr Peter R. Nelson. Thank you, Dr Baldwin, for your comments and for your review of our manuscript. I assure you that you are a candidate for PEVAR. I want to respond to one of the comments that you made. I think we have to be a little careful extrapolating these data to all endovascular devices or all large-bore access procedures since this study was conducted using a single endovascular stent graft system. I fully realize that people are using this technique for other systems, but this trial obviously was specifically focused on one device.

With respect to your first question on obesity, I think we all feel that the obese patient is really where the PEVAR technique could offer the most benefit because the obese suffer the most morbidity from groin wound complications. But, in designing a rigorous clinical trial, we have to be cautious upfront because, in the literature, the obese also have the highest complication rate of percutaneous access. So in terms of this being the first phase of the trial, it was reasonable to exclusion. The 7-cm distance required from the skin to the femoral artery was defined by the length of the micropuncture needle. We felt that if the needle could not reach the femoral artery easily, then maybe that should be an anatomic exclusion. We all know that you can indent the skin and get access in those situations, but at least for the purposes of the trial, 7 cm was the maximum length allowable.

Regarding your second question on anesthetic options used in the trial, investigators came into the trial with a certain established practice or preference in terms of what anesthetic strategy they used, and we did not see a significant change from this baseline practice. I think that if you were a local anesthetic user before, you used it in the trial. If you used general anesthetic, you used it in the trial. We did not see people switching to local anesthesia, and we did not require or suggest that in PEVAR cases. I think your point is very important, however, because this technique definitely opens the door to very feasible use of local anesthetic, which could result in even shorter hospital stays and even move us toward outpatient EVAR, and I think that is where we need to be thinking.

Your third question on iliac morphology is an important question. The trial focused most of the exclusion criteria on the common femoral artery anatomy and calcification, but we did collect data on the degree of calcification in the iliac access vessels. The amount of calcification as I showed was similar between groups and it did not impact the success of the percutaneous access overall. Greater calcification did, however, result in an increased number of iliac interventions, such angioplasties and adjunctive stenting for the access vessel. What I do in my practice is if I have someone who has a heavily calcified iliac access vessel, I still am comfortable doing percutaneous, but in that case, I might more conservatively use a series of hydrophilic dilators to sequentially dilate the access to allow the device to pass. I personally have not had problems with that affecting the success of percutaneous approach itself.

One additional comment regarding the influence of iliac anatomy is that tortuosity, which we did not critically scientifically evaluate in this trial, is a significant variable. If you have a very tortuous iliac system, and anyone who has done this will know, the Proglide device is just a little bit short, such that, in a very tortuous iliac system, you may have difficulty maintaining wire access. If the Proglide device slides back into the iliac system, you have to traverse that tortuosity twice at least to get the access and secure all of your preclosure devices. Therefore, iliac tortuosity is something I think worthy of looking at as you plan cases, since it poses some challenges that may require some thought to ensure success.

INVITED COMMENTARY

William A. Marston, MD, *Chapel Hill, NC*

As devices for endovascular aneurysm repair (EVAR) have been packaged into smaller and more flexible sheath systems, the potential for percutaneous aneurysm repair has been realized with the use of closure devices and specific pre-closure procedures.

In this carefully designed and executed prospective randomized trial, the authors have compared standard surgical femoral access EVAR (SEVAR) with percutaneous EVAR (PEVAR) using two different devices designed for femoral artery closure. Sites

were monitored for accuracy of data collection, and an independent Clinical Events Committee adjudicated adverse events. The data clearly demonstrate that PEVAR is technically feasible, and with use of the Proglide device, PEVAR was found to be statistically noninferior to SEVAR with a low incidence of access-related complications. The study selection criteria excluded patients with severe calcification, prior groin incisions, or recent use of a femoral closure device. The authors do not provide information on the frequency with which these criteria might have eliminated patients from study consideration, so it is difficult to determine the proportion of EVAR patients who might be candidates for percutaneous repair.

Although the study results support the technical success of EVAR with the Proglide device, relatively little evidence is provided that PEVAR has major advantages over SEVAR. Operative time for PEVAR was significantly shorter, but there were no significant differences between PEVAR and SEVAR in pain scores or quality of life evaluations. Whereas the average time to ambulation and hospital stay were shorter for PEVAR, the differences were not significant and appear to be of minor clinical relevance.

In summary, the results of this study provide strong evidence that PEVAR can be technically performed with a low incidence of access-related complications similar to SEVAR. Should PEVAR become the preferred method for EVAR in appropriate patients? This would require PEVAR to provide clinically relevant advantages that were not generally demonstrated in this study. It should also be noted that the study investigators were experienced vascular specialists familiar with the use of large closure devices. Some authors have suggested that the learning curve for percutaneous access for EVAR requires approximately 30 cases, but the authors of this manuscript indicate that the learning curve can be shortened to 5 to 10 cases with the use of simulators and virtual cases. Regardless, it appears that this procedure would be best performed by high-volume EVAR physicians performing enough cases to develop and to maintain the skill set to safely perform this procedure.